REMARKS

Entry of the foregoing amendments is respectfully requested.

After entry of this amendment, claims 1-45 are pending.

The claims have been amended to eliminate multiple claim dependencies and reduce the filing fees. These are not narrowing amendments.

An early and favorable examination is respectfully requested.

Respectfully submitted,

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EXPRESS MAIL CERTIFICATE

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PATENT TRADEMARK OFFICE

Docket No: 6727/0J367US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Azariah JOSSIFOFF

Serial No.: TBA (U.S. National Phase of International Application No. PCT/IL99/00619)

Filed: Concurrently Herewith

For: VAGINALLY ADMINISTRATABLE PROGESTERONE-CONTAINING TABLETS AND METHOD FOR PREPARING SAME

MARKUP ACCOMPANYING PRELIMINARY AMENDMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

May 18, 2001

Sir:

6. A method according to [any of claims 3 to 5] claim 3, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

8. A method according to claim I [any of claims 3 to 7] wherein said sieved second lubricant and said sieved third lubricant are sieved through sieves having a pore size of between about 100 and 150 microns.

10. A method according to claim 3 [any of claims 3 to 9], wherein said first lubricant is silicon dioxide (colloidal anhydrous silica).

11. A method according to claim 3 [any of claims 3 to 10], wherein said material selected from a first filler or a disintegrant is a starch exhibiting good flow properties.

14. A method according to claim 3 [any of claims 3 to 13], wherein said binder which binds dry particles is polyvinylpyrrolidone (povidone).

16. A method according to claim 3 [any of claims 3 to 15], wherein said second filler is derived from a natural source.

18. A method according to claim 3 [any of claims 3 to 17], wherein said first portion and said second portion of said second filler are of generally the same size.

19. A method according to claim 3 [any of claims 3 to 18], wherein said effervescent is prepared prior to said intimate mixing of said first portion of said second filler with said effervescent.

20. A method according to claim 3 [any of claims 3 to 18], wherein said effervescent is prepared *in situ* as part of said intimate mixing of said first portion of said second filler with said effervescent.

21. A method according to claim 3 [any of claims 3 to 20], wherein said intimate mixing of said first portion of said second filler with said effervescent comprises non-intimately mixing said first portion of said second filler with said effervescent and passing the resultant non-intimately mixed mixture through a sieve having an average pore size between about 400 and 450 microns, to obtain said third mixture.

23. A method according to claim 3 [any of claims 3 to 22] , wherein said intimate mixing of said second mixture with said third mixture to obtain said fourth mixture is accomplished by non-intimately mixing said second mixture with said third mixture to obtain a non-intimately mixed mixture and sifting said non-intimately mixed mixture through a sieve having an average pore size between about 400 and 450 microns to obtain said fourth mixture.

25. A method according to claim 3 [any of claims 3 to 24], wherein said second lubricant is selected from magnesium stearate, talc, sodium lauryl sulfate, and phosphates known in the art to function as lubricants.

27. A method according to [any of claims 3 to 26] claim 3, wherein said material selected from a saponificant or a third lubricant is sodium lauryl sulfate.

28. A method according to [any of claims 2 to 27] claim 2, wherein said effervescent is a mixture of a pharmaceutically acceptable carboxylic or dicarboxylic acid and a pharmaceutically acceptable salt of HCO_3-.

30. A method according to claim 28 [or 29], wherein said pharmaceutically acceptable salt of HCO_3- is sodium bicarbonate.

31. A method according to [any of claims 28 to 30] claim 28, wherein said pharmaceutically acceptable carboxylic or dicarboxylic acid and said bicarbonate are present in an amount providing a molar excess of -COOH groups.

32. A method according to [any of claims 28 to 31] claim 28, wherein said effervescent comprises a mixture of adipic acid and sodium bicarbonate.

33. A method according to [any of claims 2 to 32] claim 2, wherein said effervescent comprises between about 6 and 10 wt.%[, preferably about 8 wt.%] of the tablet.

34. A method according to [any of claims 1 to 33] claim 1 wherein the amount of water mixed with said micronized progesterone is between about 25 and 28 wt.% of the amount of micronized progesterone.

36. A method according to [any of claims 1 to 35] claim 1, wherein said water is added to said micronized progesterone at rate of between about 6 to 9 ml per minute.

37. A method according to [any of claims 1 to 36] claim 1, wherein said water is mixed with said micronized progesterone at a mixing speed of between about 25-33.3 rpm.

38. A method according to [any of claims 1 to 37] claim I wherein said drying of said wetted micronized progesterone is done at a temperature of between about 55°C and about 60°C.

39. A method according to [any of claims 1 to 38] claim 1 wherein all of said mixing steps are carried out at a temperature of between about 15°C and 30°C.

45. A tablet according to claim 43 [or 44] comprising between about 6 to 8 wt.% effervescent.

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